

(b) there is administrative delay (i.e. the first filed case issues second because of legitimate differences of opinion during prosecution, or administrative reasons at the Patent and Trademark Office).¹

The claims in the '974 patent are directed to a method of identifying a compound that stimulates nerve cell growth by assaying compounds for binding to a polypeptide component of a steroid receptor complex other than a steroid hormone binding portion of the complex, and assaying the compound for inhibiting assembly of the complex or promoting dissociation of the steroid receptor complex. In several embodiments (e.g., claims 3, 9, 13 and 14), the compound is an FK506 analog, but in other embodiments the compound is a benzoquinone ansamycin, a peptide comprising a sequence of a selected polypeptide component of the steroid receptor complex, an antibody that binds a selected component of the steroid receptor complex, or geldanamycin (e.g. claims 3, 4, 10, 12, 13 15, 16, and 17). The claims in the present application are directed to identifying FK506 analogs that stimulate nerve cell growth by selecting an analog that has a K_d for FKBP-12 of greater than 100 μ M.

Applicants could not have filed the claims of the two applications in a single application, because there is no support in the '887 application for assaying the compound for inhibiting assembly of the steroid receptor complex or promoting dissociation of the steroid receptor complex. In contrast, the '974 patent discloses (e.g. see column 5, lines 26-28 and column 14, lines 56-63) selection of compounds that caused the dissociation of hsp90 from the steroid receptor complex either directly (by binding to hsp90 or interfering with the binding of hsp90 to the steroid receptor) or indirectly (by binding to a polypeptide such as FKBP52 that binds to hsp90), or by preventing association of hsp90 with the steroid receptor complex. Moreover, the claims of '974 patent encompass screening compounds other than FK506 analogs, specifically to screening a benzoquinone ansamycin, a peptide comprising a sequence of a selected polypeptide component of the steroid receptor complex, an antibody that binds a selected polypeptide component of the steroid receptor complex, or a

¹ MPEP § 804 (II)(B)(1)(b), citing *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998): the two-way exception applies "when the applicant could not avoid separate filings, and...if the PTO controlled the rate of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application.", and citing *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991) : "where through no fault of the applicant, the claims in a later filed application issue first, an obvious-type double patenting rejection is improper, in the absence of a two-way obviousness determination, because the applicant does not have complete control over the rate of progress of a patent application through the Office".

geldanamycin or a derivative thereof. Screening of these compounds to identify compounds that stimulate nerve cell growth are not disclosed in the '887 application.

Thus, criterion (a) is satisfied; claims to assaying for inhibiting assembly of the complex or for promoting dissociation of the complex could not have been submitted in the present application, nor could claims to screening a benzoquinone ansamycin, a peptide comprising a sequence of a selected polypeptide component of the steroid receptor complex, an antibody that binds a component of the steroid receptor complex, or a geldanamycin derivative to identify compounds that stimulate nerve growth. As to criterion (b), issuance of the '974 patent prior to allowance of the present application is due to administrative delays at the Patent and Trademark Office. There is no evidence that Applicants have used the administrative process to assure that the second filed case issued first. Hence a determination of two-way obviousness is required in this case.

There is no two-way obviousness in this case, because the claims (claims 1-17) of the '974 patent are directed to assaying compounds for binding to a polypeptide component of a steroid receptor complex other than a steroid hormone binding portion of the complex, and assaying the compound for inhibiting assembly of the complex or promoting dissociation of the steroid receptor complex. Thus, claims 1-17 are not obvious in view of the claims of the present ('887) application, because the claims of the '887 application do not disclose or suggest the claimed method in the '974 patent in which an assay is performed for inhibiting assembly or promoting dissociation of the steroid receptor complex. Moreover, claims 3, 11, 12, 13 and 15-17 of the '974 patent recite that the test compounds are benzoquinone ansamycins, peptides comprising a sequence of a selected polypeptide component of the steroid receptor complex, antibodies that bind to the steroid receptor complex, or geldanamycin derivatives. The use of these compounds to stimulate nerve growth is not obvious in view of the claims of the present ('887) application, which are directed solely to screening FK506 analogs.

Applicants submit that in the absence of two-way obviousness, the double patenting rejection should be withdrawn.

Claim Objections

Claim 11 is rejected for depending on a rejected base claim. The Examiner has also requested that the claim be directed to assaying one or more FK506 analogs of interest. In order to comply with

this request, claim 11 is amended to recite "determining whether one or more FK506 analogs of interest has the ability to inhibit rotamase activity in order to select an FK506 analog that does not inhibit rotamase activity," as requested by the Examiner. Applicants submit that this amendment removes any objection to claim 11.

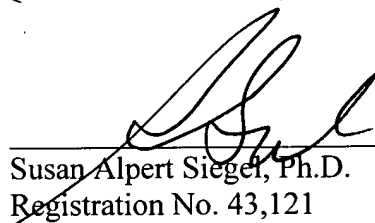
REMARKS

Applicants submit that claims 6-7, 11, 15, and 20 are in condition for allowance, which action is requested. If any minor matters remain to be addressed before a Notice of Allowance is issued, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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**Marked-up Version of Amended Claims
Pursuant to 37 C.F.R. §§ 1.121(b)-(c)**

In the claims:

Please cancel claim 19.

11. (Thrice Amended) The method of claim 6, further comprising [selecting a FK506 analog]
determining whether one or more FK506 analogs of interest has the ability to inhibit rotamase activity
in order to select an FK506 analog that does not inhibit rotamase activity.